REMARKS

This responds to the Final Office Action dated June 9, 2009 (hereinafter "Office Action"). Claims 11, 16, 19, 24, 30, 32, 36, 37, 39, 40, 43 and 44 are currently amended. Claims 1-10, 12 and 20 were previously cancelled without prejudice or disclaimer. Claims 13, 16, 18, 19, 23-28, 32, 35 and 36 were previously withdrawn. No claims are new. Accordingly, claims 11, 14, 15, 17, 21, 22, 29-31, 33, 34 and 37-44 are responded to below.

Applicant hereby respectfully requests further examination and reconsideration of this application in view of the foregoing claim amendments and following remarks.

Formal Request for Telephonic Interview

1. Per previous telephone communications with the Examiner, a telephone interview between the Examiner and Applicant's representative, Gregory Smock, is respectively requested if the present amendments and remarks do not result in allowance of all claims in the Office's next communication. As noted below, Applicant's representative can be reached by telephone at (612) 373-6956 and will make himself available at a time convenient for the Examiner.

§ 112 Rejection of the Claims

2. Claims 39 and 43 were rejected under 35 U.S.C. § 112, first paragraph, as lacking adequate description. Applicant respectfully requests reversal of this rejection based on the claims, as amended.

Claims 39 and 43:

Claims 39 and 43 have been amended to recite an ocular implant including an active agent in the form of "travaprost or bimataprost." Support for this amendment can be found at least at [0018] of the above-identified application as filed.

Reconsideration and withdrawal of this basis of rejection are respectfully requested.

3. Claims 11, 15, 17, 21, 22, 29-31, 33, 34 and 37-44 were rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness. Applicant respectfully requests reversal of this rejection based on the claims, as amended.

Claims 11, 15, 17, 21, 22, 29-31, 33, 34 and 37-44:

Independent claims 11 and 30 have been amended to recite an ocular implant including an active agent "deliverable on a sustained release basis to tissue at or near one or both of an eye or a nasolacrimal system." Support for this amendment can be found at least at [0024] of the above-identified application as filed.

Reconsideration and withdrawal of this basis of rejection are respectfully requested.

4. Claim 37 was rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness. Applicant respectfully requests reversal of this rejection based on the claim, as amended.

Claim 37:

Claim 37 has been amended to recite an "inert" implant body, which is a body that does not react with applied active agents and which does not itself provoke a response upon insertion into a subject. Support for this amendment can be found at least at [0002] and [0023] of the above-identified application as filed.

Reconsideration and withdrawal of this basis of rejection are respectfully requested.

§ *102 Rejection of the Claims*

5. Claims 11, 15, 17, 21, 22, 29-31, 33, 34 and 37 were rejected under 35 U.S.C. § 102(b) for assertedly being anticipated by Freeman (U.S. 3,949,750). Applicant respectfully requests reversal of this rejection on the ground that Freeman fails to recite each element of the claims, as amended.

According to the Federal Circuit, "[a]nticipation requires the disclosure in a single prior art reference of each element of the claim under consideration." *W.L. Gore & Assocs. v. Garlock, Inc.*, 721 F.2d 1540, 200 USPQ 303, 313 (Fed. Cir. 1983). It is not enough, however, that the reference discloses all the claimed elements in isolation. Rather, as stated by the Federal Circuit, the prior art reference must disclose each element of the claimed invention "arranged as in the claim." *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481, 485 (Fed. Cir. 1984)(emphasis added). Thus, even if the prior art reference includes all of the elements that are claimed, if the arrangement of the claimed

elements is different from the arrangement of the prior art elements, anticipation will not be present.

In constructing a rejection based on anticipation, the Examiner must identify the elements of the claims of the application, determine their meaning in light of the specification and prosecution history, and identify the corresponding elements disclosed in the allegedly anticipating reference. *Id.* When a reference relied on is subject to more than one interpretation, it is the interpretation of one of ordinary skill that is to be followed. The hypothetical person of ordinary skill is defined, in part, by considering the types of problems encountered in the art and the educational level of workers in the field. *Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 962, 1 USPQ2d 1196, 1201 (Fed. Cir. 1986).

Claim 11:

Claim 11 presently recites an ocular implant comprising, among other things, a porous or absorbent implant body and an active agent disposed "entirely throughout" the porous or absorbent implant body. Freeman, on the other hand, discloses dispensing a drug from a reservoir within a plug, but not that an entire porous or absorbent implant body stores or dispenses a medication as claimed by Applicant. For example, Freeman recites:

> In certain embodiments of the invention, the plugs 20, 20', particularly the head portion 28, 28', may be of medication-impregnable porous material such as HEMA hydrophilic polymer, or may be otherwise adapted as with capillaries or the like, to store and slowly dispense ophthalmic drugs to the eye.

(Freeman at column 5, lines 8-14; *see also*, claims 4 and 5)(emphasis added.)

In light of the teachings and objects of Freeman, which are discussed in detail below, the reservoir of Freeman does not and cannot extend beyond that used for drug delivery to an eye. Contrary to Freeman, Applicant's claimed ocular implant includes an active agent disposed "entirely throughout" a porous or absorbent implant body; and as a result, Applicant's claimed ocular implant can store a larger amount of active agent (e.g., to offer longer-term agent release) than the punctal plug of Freeman, and can allow for agent release to one or both of an eye or a nasolacrimal system.

The Office Action asserts that based on Freeman's recitations at column 5, lines 8-14, specified above, one of ordinary skill in the art would understand that the "entirety of the implant body can be made from [a medication-impregnable porous] material" similar to the implant of

Applicant's claim 11. (Office Action at page 6.) Applicant respectfully disagrees and submits that the Office Action's assertion does not interpret Freeman as would one of ordinary skill in the art. This flawed interpretation is indicated by at least the following reasons, which coincide with the 'hypothetical person of ordinary skill' factors set forth in *Custom Accessories, Inc.* (i.e., the need to consider (i) the types of problems encountered in the art and (ii) the educational level of workers in the field).

First, the problems encountered in the art and the solution offered, as explained by Freeman, expressly teach against disposing an active agent at or near the distal or deeper-inserted end portion of a punctal plug (relative to a punctal opening), in contrast to Applicant's claimed implant body having active agent disposed "entirely throughout." For example, Freeman recites that by preventing drainage of an active agent through a canaliculus, therapeutic safety can be enhanced. (*See* Freeman at column 2, lines 35-39.) Freeman further recites medication impregnating and release via plug portions configured to rest in the lacrimal lake, when implanted. For instance, Freeman recites:

> [T]he punctum plug can serve as an effective vehicle for dispensing ophthalmic medication on a sustained release basis by impregnating the plug, or a cellular member attached thereto and resting in the lacrimal lake, with medication which is slowly leached out by lacrimal fluids.
>
> The plug head is very smooth and of disc or dome shape which allows it to rest in the lacrimal lake.

(Freeman at column 2, lines 28-33 and column 5, lines 4-5; *see also*, column 6, lines 42-46 and 56-60)(emphasis added.) The way in which ocular anatomy is configured, a punctal plug head or proximal end portion can be positioned at or near a lacrimal lake when a plug distal end portion is implanted within a canaliculus; however, this distal or deeper-inserted end portion of the plug is remote and separated from the lacrimal lake when implanted.

Second, the educational level of workers in the ophthalmology field dictates that Freeman teaches against disposing an active agent at or near the distal or deeper implanted end portion of a punctal plug, in contrast to Applicant's claimed porous or absorbent implant body having active agent disposed "entirely throughout." At column 2, lines 40-43, Freeman recites that his punctal plug would allow medication, such as phospholine iodide, to be delivered to an eye yet prevent such medication from entering the nose and subsequent systemic body absorption. (*Id.*

at lines 40-43.) Workers in the ophthalmology field are well aware that phospholine iodide is a medication that must be prevented from entering the nasal or nasolacrimal systems. As one example, Medicine Online® states that use of phospholine iodide "requires digital compression of the nasolacrimal ducts for a minute or two following instillation to minimize drainage into the nasal chamber."[1] As another example, Healthopedia.com states that use of phospholine iodide requires "plac[ing] [one's] index finger over the inner corner of [the treated] eye for 1 minute [after instillation]."[2] Applicant notes that the inner corner of the eye is the location of the puncta and associated lacrimal canaliculi. Accordingly, the 'hypothetical person of ordinary skill' would not view Freeman as disclosing a plug body having active agent disposed "entirely throughout," as claimed by Applicant, since the presence of medication at or near the plug's distal or deeper-inserted end portion—absent a covering or directional polymer configuration (both of which are not disclosed in Freeman)—allows medication to leak into the nose, canaliculus or nasolacrimal system for systemic dosing or absorption. Such medication leakage, as recognized by workers in the ophthalmology field, is precisely one of the effects that Freeman is intended to prevent.

Because Freeman does not recite an ocular implant comprising a porous or absorbent implant body and an active agent disposed "entirely throughout" the implant body, as recited in Applicant's claim 11, Freeman cannot anticipate claim 11. As submitted above, Freeman clearly teaches against disposing an active agent at or near the distal or deeper-inserted end portion of his punctal plug to prevent, for example, systemic absorption of medication such as phospholine iodide. Claims 13-19, 21-29 and 37-40 are dependent on claim 11 and are patentable over Freeman for at least the reasons stated above, in addition to the elements recited in such dependent claims.

Reconsideration and allowance of claims 11, 13-19, 21-29 and 37-40 are respectfully requested.

Claim 30:

Claim 30 presently recites an ocular implant comprising, among other things, a porous or absorbent implant body "incorporating" an active agent "from a proximal end portion" to "a

[1] *See* http://www.medicineonline.com/drugs/p/2783/Phospholine-Iodide-echothiophate-iodide-for-ophthalmicsolution.html
[2] *See* http://www.healthopedia.com/drugs/quick/echothiophate-iodide/

distal end portion." In contrast, as submitted above, Freeman discloses dispensing a drug from a reservoir within a plug, but not that an entire porous or absorbent implant body stores or dispenses a medication, and furthermore, teaches against incorporating an active agent at or near the distal or deeper-inserted end portion of the punctal plug. (*See* Freeman at column 2, lines 28-39; column 5, lines 4-14; and claim 4.)

Because Freeman does not recite an ocular implant comprising a porous or absorbent implant body "incorporating" an active agent "from a proximal end portion" to "a distal end portion," as recited in Applicant's claim 30, Freeman cannot anticipate claim 30. Claims 31-36 and 41-44 are dependent on claim 30 and are patentable over Freeman for at least the reasons stated above, in addition to the elements recited in such dependent claims.

Reconsideration and allowance of claims 30-36 and 41-44 are respectfully requested.

6. Claims 11, 15, 17, 21, 22, 29-31, 33, and 37-44 were rejected under 35 U.S.C. § 102(b) for assertedly being anticipated by Cohan et al. (U.S. 6,196,993) (hereinafter "Cohan"). Applicant respectfully requests reversal of this rejection on the ground that Cohan fails to recite each element of the claims, as amended.

According to the Federal Circuit, "[a]nticipation requires the disclosure in a single prior art reference of each element of the claim under consideration."[3] In addition, the prior art reference must disclose each element of the claimed invention "arranged as in the claim."[4]

Claim 11:

Claim 11 presently recites an ocular implant comprising, among other things, "a porous or absorbent implant body," which extends "from a proximal end portion" to "a distal end portion." In contrast, Cohan recites an insert body molded or otherwise formed from a material "that is impermeable to the medication which will fill the reservoir." (Cohan at column 4, lines 28-31)(emphasis added.) In fact, the operability of Cohan relies on the insert body being impermeable, such that medication within the interior reservoir is directed out a geometry-controlled collarette pore at the insert's proximal end. For example, Cohan recites:

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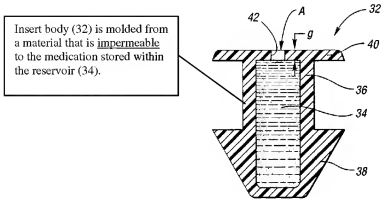
[3] *W.L. Gore & Assocs. v. Garlock, Inc.*, 721 F.2d 1540, 200 USPQ 303, 313 (Fed. Cir. 1983).
[4] *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481 (Fed. Cir. 1984) (citing *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983))(emphasis added).

> The geometry of the pore 42 leading from the reservoir 34 to the lacrimal lake 12 controls the rate of flow, I, of medication from the ophthalmic insert 32.

(Cohan at column 6, lines 31-34)(emphasis added.)



Furthermore, claim 11 presently recites an active agent disposed "entirely throughout" the porous or absorbent implant body. In contrast, Cohan—as recognized by the Office in a previous communication dated October 22, 2008 at page 6—discloses a medication reservoir within an interior surface of an impermeable insert body. For example, Cohan recites:

> A reservoir is contained at least partially within the body portion and in fluid communication with the pore, wherein the reservoir is designed to store and release medication through the pore.

(Cohan at Abstract; *see also*, column 2, lines 40-54, FIGS. 3, 7 and 9)(emphasis added.) Contrary to the interior medication storage of Cohan, Applicant's claimed ocular implant, as recited in claim 11, includes an active agent entirely throughout the porous or absorbent implant body, including at its outer periphery portions that provide a retentive shape to the implant. In this way, Applicant's claimed ocular implant can provide active agent release via an exterior surface portion of the implant body, such as at or near the implant's distal end portion. To assert that the entire body portion of Cohan could include active agent runs afoul of Cohan's reliance on the proximally-located pore to control medication release. (*See* Cohan at column 2, lines 57-60.) This controlled release via a single pore, which is emphasized throughout Cohan, is not achievable if Cohan's implant body is porous or absorbent and allows for active agent diffusion throughout, as claimed by Applicant.

The Office Action asserts that the prior form of the claims, which recited "an implant body, including a porous or absorbent material," did not require the entire implant body including agent to be made of a porous or absorbent material. (Office Action at page 7.) Accordingly, Applicant has amended the claims to recite "a porous or absorbent implant body," which extends "from a proximal end portion, configured to seat at or near a lacrimal punctum when implanted, to a distal end portion, configured for insertion through the lacrimal punctum into a lacrimal canaliculus when implanted." Applicant submits this new claim language clearly conveys that the Applicant's entire implant body including active agent is made of a porous or absorbent material, in contrast to the impermeable insert body of Cohan.

Because Cohan does not recite an ocular implant comprising "a porous or absorbent implant body," nor an active agent disposed "entirely throughout" the porous or absorbent implant body, as recited in Applicant's claim 11, Cohan cannot anticipate claim 11. Claims 13-19, 21-29 and 37-40 are dependent on claim 11 and are patentable over Cohan for at least the reasons stated above, in addition to the elements recited in such dependent claims.

Reconsideration and allowance of claims 11, 13-19, 21-29 and 37-40 are respectfully requested.

Claim 30:

Claim 30 presently recites an ocular implant comprising, among other things, "a porous or absorbent implant body," which incorporates an active agent "from a proximal end portion" to "a distal end portion of the [porous or absorbent] implant body." In contrast, as previously submitted, Cohan only discloses storing medication in a reservoir positioned within an interior surface of an insert body, and furthermore, requires the insert body to be formed of an impermeable, unsaturateable material. (*See* Cohan at Abstract; column 2, lines 40-54; column 6, lines 31-34; FIGS. 7 and 9.)

Because Cohan does not recite an ocular implant comprising "a porous or absorbent implant body," which incorporates an active agent "from a proximal end portion" to "a distal end portion of the [porous or absorbent] implant body," as recited in Applicant's claim 30, Cohan cannot anticipate claim 30. Claims 31-36 and 41-44 are dependent on claim 30 and are patentable over Cohan for at least the reasons stated above, in addition to the elements recited in such dependent claims.

Reconsideration and allowance of claims 30-36 and 41-44 are respectfully requested.

Claims 39 and 43:

Claims 39 and 43 presently recite an ocular implant including an active agent in the form of "travaprost or bimataprost." Cohan does not recite either of these active agents. Notably, the Office Action asserts that because "chemical structures are highly variant and encompass a myriad of possibilities," prostaglandin derivates other than those specifically recited in a disclosure are not supported nor predictable due to high variance. (*See* Office Action at pages 2 and 3)(emphasis added.) Accordingly, since Cohan does not specifically recite travaprost nor bimataprost, as recited in Applicant's claims 39 and 43, such reference (and other references that do not specifically recite travaprost or bimataprost) cannot be used to reject claims 39 and 43 due to the recognized high variance of chemical structures.

Reconsideration and allowance of claims 39 and 43 are respectfully requested.

§ *103 Rejection of the Claims*

7. Claims 11, 15, 17, 21, 22, 29-32, 33 and 34 were rejected under 35 U.S.C. § 103(a) as assertedly being obvious over Freeman in view of Bhushan (U.S. 2004/0137068). Applicant respectfully requests reversal of this rejection on the ground that there is no *prima facie* case of obviousness for the claims.

According to MPEP § 2142, the reference(s) must teach or suggest all of the claim elements.

Claims 11, 15, 17, 21, 22, 29-32, 33 and 34:

Claims 11 and 30 respectively recite an ocular implant comprising, among other things, "a porous or absorbent implant body" and an active agent disposed "entirely throughout" the implant body, or "a porous or absorbent implant body" incorporating an active agent "from a proximal end portion" to "a distal end portion." In contrast, as submitted above, Freeman discloses dispensing a drug from a reservoir within a plug, but not that the entire plug stores or dispenses a medication, and furthermore, teaches against incorporating an active agent at or near the distal or deeper-inserted end portion of his punctal plug. (*See* Freeman at column 2, lines 28-39; column 5, lines 4-14; and claim 4.)

Regarding Bhushan, the Office Action recognizes that such reference fails to recite an ocular implant including a porous or absorbent implant body and an active agent disposed entirely throughout the implant body. (Office Action at page 9.) For instance, the Office Action recognizes "Bhushan discloses an internal [medication] reservoir and an outer membrane." (*Id.*)

Because Freeman and Bhushan, alone or in combination, fail to teach or suggest all of the elements in Applicant's claims 11 and 30, Applicant respectfully requests reconsideration and allowance of claims 11 and 30. Claims 13-19, 21-29 and 37-40 are dependent on claim 11 and are patentable over Freeman and Bhushan for at least the reasons stated above, in addition to the elements recited in such dependent claims. Claims 31-36 and 41-44 are dependent on claim 30 and are patentable over Freeman and Bhushan for at least the reasons stated above, in addition to the elements recited in such dependent claims.

Reconsideration and allowance of claims 11, 13-19, and 21-44 are respectfully requested.

8. Claims 11, 15, 17, 21, 22, 29-31, 33, 34 and 37-44 were rejected under 35 U.S.C. § 103(a) as assertedly being obvious over Freeman in view of Cohan.

According to MPEP § 2142, the reference(s) must teach or suggest all of the claim elements.

Claims 11, 15, 17, 21, 22, 29-31, 33, 34 and 37-44:

As submitted above at sections **6.** and **7.**, Freeman and Cohan, alone or in combination, fail to teach or suggest all of the elements in Applicant's claims 11 and 30. For instance, neither Freeman nor Cohan recite an ocular implant comprising, among other things, "a porous or absorbent implant body," which extends "from a proximal end portion" to "a distal end portion," and an active agent disposed "entirely throughout" the porous or absorbent implant body.

For at least this reason, Applicant respectfully requests reconsideration and allowance of claims 11 and 30. Claims 13-19, 21-29 and 37-40 are dependent on claim 11 and are patentable over Freeman and Cohan for the reason stated above, in addition to the elements recited in such dependent claims. Claims 31-36 and 41-44 are dependent on claim 30 and are patentable over Freeman and Cohan for at least the reason stated above, in addition to the elements recited in such dependent claims.

Reconsideration and allowance of claims 11, 13-19, and 21-44 are respectfully requested.

9. Claims 11, 15, 17, 21, 22, 29-31, 33 and 37-44 were rejected under 35 U.S.C. § 103(a) as being obvious over Cohan in view of Bhushan.

According to MPEP § 2142, the reference(s) must teach or suggest all of the claim elements.

Claims 11, 15, 17, 21, 22, 29-31, 33 and 37-44:

As submitted above at sections **7.** and **8.**, Cohan and Bhushan, alone or in combination, fail to teach or suggest all of the elements in Applicant's claims 11 and 30. For instance, neither Cohan nor Bhushan recite an ocular implant comprising, among other things, "a porous or absorbent implant body," which extends "from a proximal end portion" to "a distal end portion," and an active agent disposed "entirely throughout" the porous or absorbent implant body. Rather, both Cohan and Bhushan recite an insert body having an internal reservoir for storing medication. Applicant further points out that the amount of medication that can be contained in the inserts of Cohan and Bhushan is limited to the size of the associated internal reservoir. Advantageously, the amount of medication or other active agent that can be contained in Applicant's claimed ocular implant is only limited by the size of the implant body, not the size of an internal reservoir within the body.

For at least this reason, Applicant respectfully requests reconsideration and allowance of claims 11 and 30. Claims 13-19, 21-29 and 37-40 are dependent on claim 11 and are patentable over Cohan and Bhushan for the reason stated above, in addition to the elements recited in such dependent claims. Claims 31-36 and 41-44 are dependent on claim 30 and are patentable over Cohan and Bhushan for at least the reason stated above, in addition to the elements recited in such dependent claims.

Reconsideration and allowance of claims 11, 13-19, an 21-44 are respectfully requested.

Reservation of Rights

10. In the interest of clarity and brevity, Applicant may not have equally addressed every assertion made in the Office Action; however, this does not constitute any admission or acquiescence. Applicant reserves all rights not exercised in connection with this response, such as the right to challenge or rebut any tacit or explicit characterization of any reference or of any of the present claims, or the right to challenge or rebut any asserted factual or legal basis of any

of the rejections. Applicant reserves all rights to pursue any cancelled claims in a subsequent patent application claiming the benefit of priority of the present patent application, and to request rejoinder of any withdrawn claims, as required by MPEP § 821.04.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited and encouraged to telephone Applicant's representative at (612) 373-6956 to facilitate prosecution of this application.

If necessary, please charge any additional fees or deficiencies, or credit any overpayments to Deposit Account No. 19-0743.

Respectfully submitted,

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Date October 22, 2009

By /Gregory W. Smock/
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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 22nd day of October, 2009.

DAWN M. POOLE

Name

/ Dawn M. Poole /

Signature